

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### The effect of tablet contain mixture of extract of *Vitex agnus castus*, Chamomile, *Echium amoenum* and vitamin B6 on symptoms of Premenstrual Syndrom (PMS)

#### Protocol summary

##### Summary

This study will be performed as double-blind trial, randomized, placebo-controlled by calling on 100 females collegians of Medical Sciences of Kashan University who have premenstrual syndrome, regular menstrual cycle and no signs of systemic disease or mental and physical stress before and during the study based on standard questionnaire. Before receiving drug or placebo, they will record daily symptoms for two months and after definitive diagnosis of PMS they will be divided randomly to two groups, receiveing daily tablet containing *Vitex agnus castus*, Chamomile, *Echium amoenum* extracts and Vitamin B6 or receiving placebo tablet for two months. Tables of daily symptoms forms (physical and psychological symptoms) and DSM-IV questionnaire will be completed during this time and will be consider at the end of each month. Changes in both groups will compare to baseline and also relative to each other at the end of two months.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015060812438N13**

Registration date: **2015-07-22, 1394/04/31**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-07-22, 1394/04/31

##### Registrant information

###### Name

Mohsen Taghizadeh

###### Name of organization / entity

Kashan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 36 1555 0021

###### Email address

taghizadeh\_m@kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Barij essence pharmaceutical company

##### Expected recruitment start date

2015-06-22, 1394/04/01

##### Expected recruitment end date

2016-02-20, 1394/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of tablet contain mixture of extract of *Vitex agnus castus*, Chamomile, *Echium amoenum* and vitamin B6 on symptoms of Premenstrual Syndrom (PMS)

##### Public title

The effect off *Vitex agnus castus*, Chamomile, *Echium amoenum* extracts and vitamin B6 on Premenstrual Syndrom of students from Kashan University of Medical Sciences

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion Criteria: regular menses period; no pregnancy or lactation; no history of psychological disorders; no alcohol or tobacco use; no history of systemic disorder;

no history of contraceptive use. Exclusion Criteria: Chronic disorder; Pelvic Inflammatory Disease (PID); taking specific drug; having stress such as having infection; inflammation and psychological disorder.

### Age

From **18 years** old to **35 years** old

### Gender

Female

### Phase

2-3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **100**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Used

### Assignment

Parallel

### Other design features

randomization: table of random numbers

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

##### Street address

Kashan University Of Medical Sciences, Kashan

##### City

Kashan

##### Postal code

##### Approval date

2015-03-04, 1393/12/13

##### Ethics committee reference number

29/51/1/6001/پ

## Health conditions studied

### 1

#### Description of health condition studied

premenstrual syndrom

#### ICD-10 code

N94.3

#### ICD-10 code description

Premenstrual tension syndrome

## Primary outcomes

### 1

#### Description

severity of premenstrual syndrom

#### Timepoint

Baseline and End of each months

#### Method of measurement

questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

intervention :herbal tablet made in Barij essence pharmaceutical company contain mixture of extract of Vitex agnus castus, Chamomile, Echium amoenum and vitamin B6 ,daily,for 2 months

#### Category

Treatment - Drugs

### 2

#### Description

control : placebo tablet made in Barij essence pharmaceutical company contain Cellulose,daily.for 2 months

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Kashan University of Medical Science

##### Full name of responsible person

Fatemeh Abbaszadeh

##### Street address

School of Nursing and Midwifery,Qotbe Ravandi Boulevard, Kashan

##### City

Kashan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Barij Essence Company

##### Full name of responsible person

Mohsen Taghizadeh

##### Street address

Kashan Mashhad Ardehal Road, KM44

**City**  
Kashan

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**  
Yes

**Title of funding source**  
Barij Essence Company

**Proportion provided by this source**  
100

**Public or private sector**  
*empty*

**Domestic or foreign origin**  
*empty*

**Category of foreign source of funding**  
*empty*

**Country of origin**

**Type of organization providing the funding**  
*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Kashan University of Medical Sciences

**Full name of responsible person**  
Mohsen Taghizadeh

**Position**  
PHD

**Other areas of specialty/work**

**Street address**  
School of Medicine, Qotbe Ravandi Boulevard, Kashan

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Kashan

**Postal code**

**Phone**  
+98 31 5554 0021

**Fax**

**Email**  
taghizadeh\_m@kaums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Kashan University of Medical Sciences

**Full name of responsible person**  
Fatemeh Abbaszadeh

**Position**

Master of midwifery

**Other areas of specialty/work**

**Street address**  
School of Nursing and Midwifery, Qotbe Ravandi Boulevard, Kashan

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abbaszadeh\_F@kaums.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Barij Research Center of Medicinal Herbs

**Full name of responsible person**  
Mahnaz.Mahlouji

**Position**  
Clinical Expert

**Other areas of specialty/work**

**Street address**  
Kashan Mashhad Ardehal Road, KM44

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**Phone**  
00

**Fax**

**Email**  
mahnaz.mahlouji@yahoo.com

**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
*empty*

**Study Protocol**  
*empty*

**Statistical Analysis Plan**  
*empty*

**Informed Consent Form**  
*empty*

**Clinical Study Report**  
*empty*

**Analytic Code**  
*empty*

**Data Dictionary**  
*empty*